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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1119421

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

August 11, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Timothy Robert Giles Sear
President and CEO
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Mr. Sear:

During an inspection of your firm located in Huntington, West Virginia, conducted May 2 to June 10, 1998 by the Food and Drug Administration (FDA), our investigator determined that your firm manufactures intraocular lenses. Intraocular lenses (IOLs) are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to submit information to the FDA as required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR, Part 803, of the Act. Specifically, you failed to submit four MDR reports to FDA after receiving information that reasonably suggested that your commercially distributed device may have caused or contributed to serious injury or had malfunctioned and would be likely to cause or contribute to a serious injury if the malfunction were to recur.

On October 20, 1997, your firm received a report regarding a patient from whose eye a lens was sugically removed because it had torn in two places while in the patient's eye. On December 19, 1997, your firm received a complaint regarding a patient whose lens had been explanted from their eye during a second surgical procedure and replaced with another lens because the initial lens had cracked. On March 20, 1998, your firm received a complaint regarding a patient whose surgical incision had to be widened to remove an IOL which would not unfold in the eye after implantation. On April 20, 1998, your firm received another

complaint regarding a patient whose surgical incision had to be widened to remove an IOL which had cracked.

An MDR report is required within 30 days of becoming aware of information that reasonably suggests that a device has or may have caused a reportable event unless the firm obtains information to the contrary (21 CFR 803.20). Once in receipt of "information that reasonably suggests," the firm cannot wait (past the 30 day timeframe) for confirmation before submitting an MDR report.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 (enclosed) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

We acknowledge that Mr. Gary G. Heidel for Ms. Rebecca G. Walker, Senior Director, Regulatory Compliance, submitted to this office a response dated June 17, 1998, concerning our investigator's observations noted on the Form FDA-483. Based upon our subsequent contact with Mr. Heidel, we acknowledge that your firm has submitted MDR reports for those incidences listed on the FDA-483.

You should take prompt action to correct these deviations whether identified by our investigator or through your internal systems audit. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,

Carl E. Draper

Carl E. Draper
Acting Director, Baltimore District

cc: Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215-2299